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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,152	09/25/2006	Xin-Yun Huang	2003080-0205 (SK-1071-US2)	4442
63411	7590	02/13/2009	EXAMINER	
CHOATE, HALL & STEWART LLP			HAVLIN, ROBERT H	
SLOAN-KETTERING INSTITUTE FOR CANCER RESEARCH			ART UNIT	PAPER NUMBER
TWO INTERNATIONAL PLACE			1626	
BOSTON, MA 02110				

MAIL DATE	DELIVERY MODE
02/13/2009	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/551,152	HUANG ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	ROBERT HAVLIN	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 05 December 2008.
- 2a) This action is **FINAL**.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-62 is/are pending in the application.
- 4a) Of the above claim(s) 13,15,21-26,28,29 and 31-40 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1,11,16,27,43,44 and 48-62 is/are rejected.
- 7) Claim(s) 2-10,12,14,17-20,30,41,42 and 45-47 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 28 September 2005 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____ .
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)	5) <input type="checkbox"/> Notice of Informal Patent Application
Paper No(s)/Mail Date _____ .	6) <input type="checkbox"/> Other: _____ .

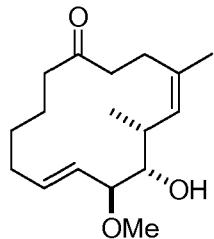
## DETAILED ACTION

**Status of the claims:** Claims 1-62 are currently pending.

**Priority:** This application is a 371 of PCT/US04/09380 (03/26/2004) which claims benefit of 60/458,827 (03/28/2003) and claims benefit of 60/496,165 (08/19/2003).

### ***Election/Restrictions***

1. Applicant previously elected the following species (stated to read on claims 1-12, 14, 16-20, 27, 30, 41-62):



Because the generic claim 1 was found unpatentable, in accordance with the requirement for restriction and election of species practice, the claims are hereby restricted to the elected species only. Claims 13, 15, 21-26, 28, 29, 31-40 are withdrawn because they do not read on the elected species.

### **RESPONSE TO APPLICANT REMARKS**

#### ***35 USC § 102***

2. Claim 1 was rejected under 35 U.S.C. 102(b) as being anticipated by Nakamura et al. (Journal of Antibiotics (2002), 55(4), 442-444).

Applicant has amended the claims around this rejection by narrowing the scope of “Q”, therefore **the rejection is withdrawn**.

3. Claims 1-12, 14, 16-19, 27, and 30 were rejected under 35 U.S.C. 102(a) as being anticipated by Gaul et al. (Gaul, Christoph; Danishefsky, Samuel J. Tetrahedron Letters (2002), 43(50), 9039-9042; listed in IDS; available online 11/9/2002).

Applicant added a proviso to the claims to avoid this prior art, therefore **this rejection is withdrawn.**

***Claim Rejections - 35 USC § 112***

4. Claims 1-40, 43-57, 60-62 were rejected under 35 USC 112 1<sup>st</sup> paragraph as failing to comply with the written description requirement.

Applicant amended the scope of the claims to be commensurate with the support in the disclosure, therefore **this rejection is withdrawn.**

5. Claims 48-62 were rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for treating breast tumor metastasis in a subject. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Applicant has narrowed the scope of the claims, however, the data potentially supporting a method for treating a breast tumor was still far more narrow than the scope of the claims. This conclusion was based on the few data points provided on a very limited number of compounds in the specification. If applicant has a data compilation supporting the enablement of the claimed scope, the examiner would be willing to withdraw the rejection. Nevertheless, absent a more substantial showing of support, **the rejection is maintained.**

6. Claims 43 and 44 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant argues one of ordinary skill in the art would know what “an amount effective to inhibit metastasis/angiogenesis” is. As described above, there is not a sufficient disclosure to support enablement of the method of treating breast cancer as it would require undue experimentation, similarly, one of ordinary skill in the art would need to practice undue experimentation to arrive at the appropriate dosage level. Furthermore, applicant points to paragraphs [0306-08] as specific dosage level embodiments, however the paragraphs referred to lack and reference to a specific compound. As is well known in the art, dosage levels are very unpredictable and highly dependent on the physicochemical characteristics of the individual molecule. Therefore, one of ordinary skill in the art would be required to practice undue experimentation and **this rejection in maintained.**

### **NEW CLAIM REJECTIONS**

#### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 11, 16, 27, are rejected under 35 U.S.C. 102(b) as being anticipated by GB 1036084.

The prior art teaches 7-hydroxycyclotetradecanone which is a member of the genus of the claims.

#### ***Claim Objections***

The remaining pending claims not rejected are objected to for reading outside the scope of the elected species only and being dependent on a rejected base claim.

***Conclusion***

No claim is in condition for allowance. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT HAVLIN whose telephone number is (571)272-9066. The examiner can normally be reached on Mon. - Fri., 7:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful the examiner's supervisor, Joe McKane can be reached at (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert Havlin/  
Examiner, Art Unit 1626

/Rebecca L Anderson/  
Primary Examiner, Art Unit 1626